

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Kovesdi et al.

Application No. 09/599,997

Art Unit: 1636

Examiner: McKelvey, T.

Filed: June 23, 2000

For: VIRAL VECTOR ENCODING  
PIGMENT EPITHELIAL DERIVED  
FACTOR

**PENDING CLAIMS AFTER AMENDMENTS  
MADE IN RESPONSE TO OFFICE ACTION DATED APRIL 9, 2002**

1. An adenoviral vector comprising a nucleic acid sequence encoding pigment epithelium-derived factor (PEDF) or a therapeutic fragment thereof, wherein the nucleic acid sequence is operably linked to regulatory sequences necessary for expression of PEDF or a therapeutic fragment thereof.

3. The adenoviral vector of claim 1, wherein the adenoviral vector is replication deficient.

4. The adenoviral vector of claim 3, wherein the adenoviral vector is lacking all or part of the E1 region.

5. The adenoviral vector of claim 4, wherein the adenoviral vector is lacking all or part of the E1a region and/or is lacking all or part of the E1b region.

6. The adenoviral vector of claim 3, wherein the adenoviral vector is lacking all or part of the E4 region.

7. The adenoviral vector of claim 3, wherein the adenoviral vector is multiply-deficient.

8. The adenoviral vector of claim 7, wherein the adenoviral vector is lacking all or part of the E1 region, all or part of the E3 region, and all or part of the E4 region.

9. The adenoviral vector of claim 7, wherein the adenoviral vector is lacking all or part of the E1 region, all or part of the E2 region, and all or part of the E3 region.

10. The adenoviral vector of claim 9, wherein the adenoviral vector is further lacking all or part of the E4 region.

11. The adenoviral vector of claim 8, wherein the adenoviral vector comprises a nucleic acid sequence encoding a cis-acting factor, wherein the cis-acting factor modulates the expression of the nucleic acid sequence encoding PEDF or a therapeutic fragment thereof.

12. The adenoviral vector of claim 11, wherein the cis-acting factor is a MAR sequence or a LCR sequence.

13. The adenoviral vector of claim 8, wherein the adenoviral vector further comprises a nucleic acid sequence encoding a trans-acting factor, wherein the trans-acting factor modulates the expression of the nucleic acid sequence encoding PEDF or a therapeutic fragment thereof, and wherein the nucleic acid sequence encoding a trans-acting factor does not encode an adenoviral E4 region gene product.

14. The adenoviral vector of claim 13, wherein the trans-acting factor is selected from the group consisting of HSV ICP0, Ad pTP, CMV UL84, VZV-ORF61, PRV-EP0, CMV-E1, CMV-IE2, CMV-IE86, HIV-tat, HTLV-tax, HBV-X, and AAV-Rep 78.

15. The adenoviral vector of claim 1, wherein the regulatory sequences comprise a promoter selected from the group consisting of a CMV promoter, an RSV promoter, an adeno-associated virus-p5 promoter, a Lac2 promoter, an EF1 $\alpha$  promoter, and a  $\beta$ -actin promoter.

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24. The adenoviral vector of claim 21, wherein one or more additional nucleic acid sequences encodes an anti-angiogenic substance.

25. The adenoviral vector of claim 24, wherein the anti-angiogenic substance is a soluble receptor specific for an angiogenic factor.

26. The adenoviral vector of claim 25, wherein the soluble receptor specific for an angiogenic factor is a soluble VEGF-R1 receptor.

27. The viral vector of claim 21, wherein the therapeutic substances other than PEDF or a therapeutic fragment thereof are linked to an endoplasmic reticulum localization signal peptide.



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